

Remarks

Claim Status

With the entry of this amendment, claims 1, 3-7, 9, 11, 14-16 and 18 will be pending, with claims 3-5 withdrawn, and claims 2, 8, 10, 12-13, 17 and 19-26 will be canceled. Claims 1 and 9 will be amended. No new matter has been added by amending these claims.

Rejections Under 35 U.S.C. § 112, ¶2

The Office rejected claims 1, 5 and 6 as indefinite. Applicant herein amends the phrase "and or" in claim 1 to recite "and/or" and accordingly requests that the Office withdraw the rejection.

The Office also rejected claims 1, 2-6, 11-13 and 18-26 as indefinite. Applicant herein amends "N" to "n" in the context of R(CH<sub>2</sub>)<sub>n</sub> and thanks the Examiner for examining the claims with the understanding that "n" is defined as 0-3 and "N" is a nitrogen atom.

Rejection Under 35 U.S.C. § 103

The Office issued new grounds for rejection, alleging that claims 1, 6-9, 11-13 and 18-26 are unpatentable over Villhauer, in view of Luskey.

Applicant claims the compounds of Formula I for the treatment of hyperlipidemia. The Office asserted that Villhauer teaches that the compound of Formula 1C can be used to treat diabetes and that Luskey teaches hyperlipidemia as a precipitating factor in some patients with diabetes. According to the Office, it would be *prima facie* obvious to treat hyperlipidemic patients with the compound of Formula I because this compound can treat diabetes in a subset of diabetic patients. Office Action at page 6.

Applicant traverses the rejection and amends the claims solely to advance prosecution, reserving the right to file additional applications directed to the presently claimed subject matter. It would not be obvious to one skilled in the art to combine the teaching of Villhauer, that the compound of Formula I treats diabetes, with that of Luskey, which teaches that derivatives of halofenic acid can be used to treat hyperlipidemia. These references, considered alone or in combination, contain no teaching, suggestion or motivation to use the compound of Formula I to treat hyperlipidemia. At most, hyperlipidemia is one of many contributing factors that contribute to the development of diabetes in some patients.

The Office also alleges that the claimed invention is obvious in view of the combination therapies taught by Luskey. Office Action at page 7. Luskey teaches combinations of halofenic acid derivatives with anti-hyperlipidemic agents to treat atherosclerosis and combinations of halofenic acid derivatives with anti-diabetic agents to treat diabetes. It does not teach or suggest the use of the compound of Formula I to treat hyperlipidemia. Accordingly, Applicant

respectfully requests that the Office withdraw its rejection of the claims, under 35 U.S.C. § 103(a).

**Double Patenting**

Claims 1, 6-9, 11-13 and 18-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claim 6 of co-pending commonly owned U.S. Patent Application No. 11/815,536, or claim 8 of co-pending commonly owned U.S. Patent Application No. 11/497,130. Applicants request that this rejection be deferred pending some identification of allowable subject matter, at which time applicants will consider the filing of a suitable terminal disclaimer.

**Conclusion**

Applicants believe that the foregoing constitutes a complete and full response to the Action of record. If there are any issues that can be resolved by a telephone conference, the Examiner is invited to call the undersigned attorney.

The Commissioner is hereby authorized to charge any fees required to Deposit Account No. 19-0134 in the name of Novartis.

Respectfully submitted,



Cozette M. McAvoy  
Attorney for Applicant  
Reg. No. 60,457

Novartis Pharmaceuticals Corporation  
One Health Plaza, Bldg. 101  
East Hanover, NJ 07936  
(862) 778-9273

Date: April 13, 2010